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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
12/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,484	KOSUGI ET AL.	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,17,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,17,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/19/09; 11/3/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment Entry

1. Applicant's amendment and response filed XXX is acknowledged and has been entered. Claim 1, 16, and 18-29 have been cancelled. Claims 15 and 17 have been amended. Claims 30 and 31 have been added. Accordingly, claims 15, 17, 30 and 31 are pending and are under examination.

Withdrawn Rejections / Objections

2. The rejections of claim 1 are now moot in light of Applicant's cancellation of the claim.

3. In light of Applicant's argument and submission of Declaration under 37 CFR § 1.132, the rejections of claims 15 and 17 under 35 U.S.C. 103(a) as being unpatentable over Oikawa et al. (Journal of Pathology 199: 318-323 (January 13, 2003)) in view of Hochstrasser et al. (WO 94/12881)), is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15, 17, 30, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30, preamble, is vague and indefinite in reciting, "A method of diagnosing endometriosis or a disease caused by endometriosis in a subject" comprising the recited measuring step and comparing step because it is unclear how the distinct conditions: endometriosis, a disease caused by endometriosis, and risk for endometriosis, are differentially diagnosed. It appears that the same method steps are used to diagnose any one of endometriosis, a disease caused by endometriosis, or risk of endometriosis; hence, it is unclear based on the method steps and limitations provided, how one condition can be differentiated from the other.

Regarding claim 30, the phrase "a disease caused by endometriosis " renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "a disease caused by endometriosis"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). What diseases are encompassed by the recitation?

Claim 30 is indefinite in reciting "an amount of HRF protein in a control" because it is unclear what the term "control" is intended to encompass as used in the claim, especially that it is used in a comparison step to provide diagnosis of a disease. Does Applicant intend the "control" to be a normal control? See also claim 15.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 15, 17, 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Hochstrasser et al. (WO 94/12881)).

Hochstrasser et al. teach an immunological method to detect a marker protein designated as Translationally Controlled Tumor Protein p21 (TCTPp21) present in growing cells (Abstract). Immunological methods include fluorescent immunoassays and ELISA. Increase of this marker protein in growing cells provides indication of active cell growth which in cancer conditions, i.e. ovarian cancer cells and cervical cancer cells, is unregulated. Hochstrasser et al. specifically teach generating antibodies specific to TCTPp21 and using these anti-TCTPp21 antibodies to detect TCTPp21 present in the cells. TCTPp21 may also be expected in lymph nodes or body fluid of patients (p. 1 line 9 to p. 2, line 5; and p. 4, lines 24-34). Where cell tissues are obtained, Hochstrasser et al. teach lysing the cells so as to release or expose the TCTPp21 protein and use the lysate in immunoassay to detect the TCTPp21 protein (p. 4, line 35 to p. 5, line 4 and p. 6, lines 14-19). The sample is contacted with a first anti-TCTPp21 antibody that is immobilized to a solid support (ELISA plate) and that binds to an epitope of the TCTPp21 protein. After the plate containing the sample is incubated and then washed, the sample is further contacted to a second anti-TCTPp21 protein antibody that is conjugated to a fluorescent or enzyme label and that binds to another epitope on the TCTPp21 protein to label the protein bound to the solid support. The labeled resulting complex on the support is measured so as to obtain a concentration of the TCTPp21 protein and then compared to normal TCTPp21 protein control levels (p.

12, Example 2). The first antibody and the second antibody may be polyclonal or monoclonal and are generated from TCTPp21 immunogen or peptide fragment thereof which comprises a peptide having a sequence of 5-20 amino acid residues (16 AA residues: GKLEEQRPERVKPFMT) within 1-41 amino acid positions of TCTPp21 protein.

In as far as the histamine-releasing factor or HRF protein (SEQ ID No. 2) and antibodies specific thereto recited in claims 15 and 17, the amino acid residues of TCTP21 immunogen as taught by Hochstrasser et al. in 1-41 AA positions is 100% homologous to the amino acid residues within 90 to 130 AA positions of SEQ ID No. 2 (p. 6, lines 7-13).

Regarding the interpretive "wherein" clause recited in claim 30 ("wherein an increase in the amount of HRF protein in the sample from the subject as compared to the amount of HRF protein in the control, (1) indicates endometriosis or a disease caused by endometriosis ... or (2) correlates with risk for endometriosis..."), the clause does not recite any additional active method steps, but simply states a characterization or conclusion of the results of those steps. Therefore, the "wherein" clause is not considered to further limit the method defined by the claim and has not been given weight in construing the claims. See Texas Instruments, Inc. v. International Trade Comm., 988 F.2d 1165, 1171, 26 USPQ2d 1018, 1023 (Fed Cir. 1993) ("A 'whereby / wherein' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim."). See also Minton v. National Assoc. of Securities Dealers, Inc., 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)

("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.").

Accordingly, it is deemed that Hochstrasser et al. anticipates the claimed invention.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant recites use of antibodies obtained by using a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid positions 90 to 130 of SEQ ID NO: 2" which is an immunizing antigen, for binding HRF protein present in a subject to provide diagnosis of endometriosis. Although one of skill in the art might realize from reading the disclosure that antibodies elicited by using a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid positions 101-116 of SEQ ID NO: 2 are useable in the invention, such possibility of use does not provide explicit or implicit indication to one of skill in the art that antibodies that bind to

HRF protein as claimed in claim 17, were originally contemplated as part of Appellant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph.

The specification fails to provide adequate written description for antibodies obtained by using a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid positions 90 to 130 of SEQ ID NO: 2" which is an immunizing antigen, for binding HRF protein present in a subject to provide diagnosis of endometriosis because it does not disclose adequate representative species of such antibodies described by structure, physical or chemical characteristics, in Applicant's disclosure and working examples, sufficient in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that Applicant had possession of the claimed invention at the time of filing to establish that the Applicant had possession of the claimed invention. See the Interim Guidelines on Written Description (Fed Reg, June 15, 1998, Volume 63, Number 114, pages 32639-32645).

Adequate written description requires more than a mere statement of requisite use of peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid positions 90 to 130 of SEQ ID NO: 2 and antibodies therefor, in a diagnostic assay for endometriosis as part of the invention and a reference to a potential method of making it. The nuclei acid itself is required. See Fiers v. Revel, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Lts., 18 USPQ2d 1016.

Possession may be shown by describing the invention with sufficient relevant teaching and identifying the characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

December 2, 2009